of *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

(ii) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus,* soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

[67 FR 54954, Aug. 27, 2002, as amended at 68 FR 55824, Sept. 29, 2003; 69 FR 32273, June 9, 2004]

§ 520.447 Clindamycin liquid.

(a) *Specifications.* Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 000009 and 059130 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), and (d)(2)(ii)(A) of this section.

(2) No. 059079 for use as in paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), (d)(2)(i)(B), and (d)(2)(ii)(B) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.

(B) Wounds, abscesses, and dental infections: 2.5 mg per pound (/lb) of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 mg/lb of body weight every 12 hours for a minimum of 28 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*), deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens,* dental infections due to susceptible strains of *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens,* and osteomyelitis due to susceptible strains of *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

(B) For the treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *S. aureus* and for soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

(2) Cats—(i) *Amount*—(A) 5.0 to 15.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(B) 5.0 to 10.0 mg/lb of body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use*—(A) For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *S. aureus, S. intermedius, Streptococcus* spp., deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis,* and dental infections due to susceptible strains of *S. aureus, S. intermedius, Streptococcus* spp., *C. perfringens,* and *B. fragilis.*

(B) Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *S. aureus, S. intermedius,* and *Streptococcus* spp. Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *C. perfringens* and *B. fragilis.*

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004]

§ 520.452 Clenbuterol syrup.

(a) *Specifications.* Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per

100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is nonresponder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use.* Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations.* Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine hydrochloride tablets.

(a) *Specifications.* Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use.* For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 1762, Jan. 12, 1999]

§ 520.462 Clorsulon drench.

(a) *Specifications.* The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use. Cattle*—(1) *Amount.* One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use.* For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.522 Cyclosporine.

(a) *Specifications.* Each capsule contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 5 mg per kilogram of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(2) *Indications for use.* For the control of atopic dermatitis in dogs weighing at least 4 pounds body weight.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 54804, Sept. 19, 2003]